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09/780,901	02/09/2001	Charlene A. Boehm	46607-248184	6758

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,901	BOEHM, CHARLENE A.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendments filed 6/13/05 have been entered. Claims 1-2 and 4-14 are pending. All rejections and objections not reiterated below are hereby withdrawn. All rejections set forth below are necessitated by amendment.

The declaration and arguments filed 6/13/05 have been fully considered. It is noted that multiple references were appended to the arguments but were not listed on a Form 1449 (IDS). Applicant is reminded that references will not be made "of record" unless they are properly cited on a Form 1449.

The examiner appreciates applicant's attempt to clarify many issues by amending the specification. Unfortunately, it appears that these efforts have resulted in the addition of much new matter to the specification, in particular new pages 20-23. See below. It is noted that the applicant admits on the first page of the "Remarks" (page 14 of the response) that the procedure has been "expanded". This is equivalent to admitting that new matter has been added. It is further noted that applicant admits on pages 15-16 that the terms "genomic material" and "base pairs" implies particular limitations, and has changed claim language to broaden the claimed limitations. While the examiner understands that applicant does not wish her claims to be so limited, she reminds applicant that any limitation must be FULLY supported by the originally filed disclosure. As nucleic acid chains, generically, are not fully supported by the original disclosure of specific types of DNA and mRNA (see below), the amendments which broaden the scope of the claims also introduce new matter.

If applicant desires to introduce new matter, she may do so by filing the application (with new mater added) as a CIP (continuation-in-part) application under 37

CFR 1.53 (b). See MPEP 201.08. Otherwise, all new matter must be deleted. See MPEP 608.04 for a discussion of new matter.

Specification

The amendment filed 6/13/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Use of the inventive method for "genomes of pathogens", or for genomic materials "composed of DNA or RNA" is new matter. The original specification disclosed genomes of specific pathogens (e.g. Borrelia), not generically "genomes of pathogens". The original specification and claims disclosed "genomic material" and mRNA (see below), but not any other type of DNA or RNA. The broader disclosure of page 1 is therefore new matter.

The disclosure for frequency of frequencies "from a plasma emission device", as set forth on amended page 2, is new matter. Neither the original specification nor claims disclosed or recited a "plasma emission device".

The use of "electric fields" alone or in combination with magnetic fields, and "audio-range, radio-range, and light-range frequency waves", as set forth on page 3, is new matter. The original specification and claims did not disclose these types of radiation anywhere. Page 4 of the original specification disclosed "musical notes" but not "audio-range frequencies" or "sound waves". A "note" may be an annotation on

paper and is not necessarily an "audio-range frequency", therefore the "musical notes" do not provide support for "audio-range frequencies" or "sound waves", and both pages 3 and 4 disclose new matter.

All of the material added to pages 21-23 is new matter. There is no support anywhere for the steps or calculations newly disclosed, therefore it is new matter.

The amendments to the remainder of the specification are replete with new matter. In the interests of environmental conservation, the examiner will not list every example herein, but encourages applicant to carefully review both the original specification and the amendments to ensure that adequate support is provided for the amended material. The examiner invites applicant to request an interview if she desires aid in determining what is or is not supported.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, 1st para.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 1 recites multiple instance of new matter, as set forth below.

With regard to all pending claims, a nucleic acid chain consisting of anything but genomic DNA or mRNA for use in the claimed method is new matter.

With regard to claim 4, a step of obtaining a "unique electrical permittivity value" for a medium is new matter.

With regard to claim 1, a method of determining resonant frequencies of electromagnetic radiation for influencing a medium surrounding a target nucleic acid is new matter. Original claims 1 and 15 were directed to methods of determining resonant frequencies of electromagnetic radiation for influencing a target genomic material, and did not recite any limitations for "influencing a medium". Original dependant claims 4 and 5, for example, limited a surrounding medium to tissue and recited steps of determining the velocity and refractive index of electromagnetic radiation through the medium/tissue, but did not recite any limitations with regard to "influencing" the medium; i.e. the steps of the original claims appear to be calculations of how the medium affects (or influences) the electromagnetic radiation. These limitations do not provide support for a method, or any steps, of determining frequencies of electromagnetic radiation which influence a *medium* surrounding a genomic material or any other nucleic acid. The originally filed specification, on page 7, provides literal support for the phrasing of the preamble of amended claim 1. However, nowhere does the originally filed specification actually teach a method, or any steps, for determining resonant frequencies of electromagnetic emission which influence the *medium* surrounding a

nucleic acid chain of any kind. In fact, the entirety of the disclosure is directed to determining a starting emission frequency which is *corrected* for the effects of the medium ON the radiation, such that when the starting emission frequency is altered by passing through the medium, it is "tuned" correctly to the target nucleic acid. Thus, although the originally filed specification provides literal support for the newly recited phrase, it does not provide a full and complete description of the newly claimed method. For these reasons, a method of determining resonant frequencies of electromagnetic radiation for influencing a medium surrounding a target nucleic acid is new matter, and the claims are rejected.

A method for determining resonant frequencies of electromagnetic radiation which affect any nucleic acid chain other than DNA, mRNA or "genomic material", as recited in claim 1, is new matter. The original claims recited "genomic material" and "base pairs" and therefore were interpreted to be directed only to double-stranded genomic DNA. The original claims did not recite any generic "nucleic acid chains", RNA, any single-stranded nucleic acids, etc. The originally filed specification also discloses "genomic material" throughout the disclosure, and specifically discloses DNA on pages 13 and 20. mRNA is specifically disclosed on page 22, thus the specification provides support for DNA and mRNA, but does not provide specific support for any single-stranded nucleic acid or any nucleic acid "chain" other than DNA or mRNA. It is noted that mRNA may be double stranded where it is hybridized to a complementary strand (e.g. DNA), thus the disclosure for mRNA is not specific support for a "single-

stranded" nucleic acid, which is a broader limitation. While "DNA" may encompass a variety of different embodiments, it is noted that none of those embodiments is specifically disclosed, thus the broader limitations of "nucleic acid chain" is not supported by the narrower disclosure for DNA.

As neither the original claims nor specification provide support for the broader limitation of "nucleic acid chain" or for the limitations with regard to "single stranded molecules", nor for the broader limitation of "ribonucleic acid", claim 1 recites new matter.

A device capable of producing a "frequency influenced electric field, or magnetic field, or electromagnetic field, or electrical current emission", as in amended claim 1, is not supported anywhere. Both the original claims and specification recited and disclosed only a "frequency emitting device" , thus the device was certainly one "capable of" emitting some type of radiation. The original specification disclosed "magnetic fields" as a prior art method of inhibiting microbial growth, but did not specifically disclose a "device capable of producing" these waves for use in the inventive method. As the particular frequency, "field" or "emission" type for the claimed device was not disclosed/limited, the new limitations are not supported by the originally filed disclosure, and the claims recite new matter.

Determination of a length "parameter" for a target "nucleic acid chain", newly recited in claim 1, is not supported. See also the discussion above with regard to

nucleic acid chains and the rejection below under 35 USC 112, 2nd regarding a "parameter". Even where the claims read on DNA, determination of a length parameter is new matter. The original claims did not recite calculating or determining a length "parameter" anywhere. The originally filed specification, on page 13 and 20, discloses multiplying a number of bases in a DNA chain by the average spacing a base pairs to determining the total length of a genome. This is a number which must be calculated for every "genome" and thus is not a "parameter" or constant which may be carried across different experiments. AS neither the originally filed specification or claims provides support for a step of determining a "length parameter", the claims recite new matter and are rejected.

A step of determining a number of nucleotide *bases* in a *single strand* of a target nucleic acid chain, and of multiplying the number of bases by the average spacing of the bases, is new matter. Original claim 1 recited obtaining the number of "base pairs" in a "genomic material" and multiplying that number by the average spacing between "base pairs". Pages 13 and 20 of the specification provide examples wherein the number of base pairs in a genome is determined and multiplied by an average base pair spacing, thus reflecting the language of the original claims. It is admitted that page 20 discloses viral DNA, and that viral DNA MAY be single stranded. However, under certain circumstances, viral DNA may also exist in double-stranded form, thus the disclosure on page 20 for viral DNA is not necessarily a disclosure for a single stranded nucleic acid chain, and is not a "clear" or "typographical" error wherein one skilled in the

art would have been apprised that applicant intended to calculate the number of individual bases in a single strand. There is no specific disclosure anywhere for calculating the number of nucleic acid bases in a single stranded chain. The specification ONLY discloses multiplying by the average spacing of "base pairs" and does not disclose multiplying by the average spacing or nucleic acid bases anywhere. Thus, none of the steps nor the entirety of obtaining a number of nucleic acid bases in a single strand of a target nucleic acid chain, and multiplying that by the average spacing of nucleotide bases is supported by the originally filed specification or claims, therefore the claims recite new matter and are rejected.

A limitation excluding a number of nucleic acid bases in a complementary strand is new matter. Applicant is reminded that a negative limitation must be as fully and specifically supported as any positive limitation. In the instant case, the original claims did not recite, and the originally filed specification does not recite any limitation excluding complementary bases, thus this limitation is new matter.

A "medium-sensitive target nucleic acid chain" is new matter. It is not clear what this phrase means (see below). In addition, no "medium-sensitive" nucleic acid is recited or disclosed anywhere in the originally filed specification or claims. As set forth above, the entirety of the disclosure is directed to correcting a radiation frequency for the effects of a medium of that frequency. Thus, it appears that the *radiation* is

"sensitive" to the medium, not the target itself. As the originally filed disclosure fails to provide support for this phrase, the claims recite new matter and are rejected.

A step of dividing a number of nucleotide bases into a constant, wherein the constant is a "shortened version" of a mathematical procedure" is new matter. The originally filed specification, on pages 13 and 20, discloses dividing a velocity by a calculated length of a genome. While the velocity is a constant, it is not divided by a NUMBER of nucleotide bases. The velocity constant may be any of several different numbers, as disclosed on pages 13-15, which are calculated according to any of several different equations. A constant, or result of a mathematical equation, is not generally interpreted by those in the art to be a "shortened version" of an equation or algorithm. A "shortened version" is generally interpreted to be equivalent to a simplified equation; e.g. wherein certain variables are removed, or held to be zero or one, such that only critical elements/variables are considered. Thus, while the originally filed specification does provide support for dividing a constant by a *length* of a genomic target material, there is not disclosure or recitation anywhere for dividing a constant by a number of bases. Further, there is no disclosure anywhere for a "constant" which is a "shortened version" of an "entire mathematical procedure".

Where claims 2 and 4-14 recite terms similar to those above, they are also rejected for reciting new matter. In addition, because claims 2 and 4-14 depend from claim 1, they are also rejected for reciting new matter.

Specifically with regard to claim 4, a step of obtaining a "unique electrical permittivity value" for a medium is new matter. Original claim 4 limited a medium to have a "unique electrical permittivity", and related that "permittivity" to velocity, but nowhere recited "obtaining" a unique electrical permittivity value. In fact, the "unique permittivity value" is not defined anywhere. An "electrical permittivity", as set forth in original claim 4 and on page 14 of the originally filed specification, is interpreted to be capacitance, based on the units of "farads/meter" disclosed on page 14. Thus a "unique permittivity value" is interpreted to be the capacitance of a particular medium. As this value may be previously known, the mere fact that this value is "accounted for" in the original claims and specification does not support an active step of "obtaining" such a value. Further, ϵ_0 is defined in the original claims and specification as merely the "electrical permittivity", not as "the electrical permittivity of the medium" as now recited in amended claim 4. Similarly, μ_0 is defined as the "magnetic permeability" and not as the "magnetic permeability of the medium" as newly recited in amended claim 4. It is noted that the variables originally disclosed are ϵ_0 and μ_0, therefore both the recitation and definition of terms μ and ϵ are new matter.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The amended claims are directed to a method of influencing a medium surrounding a target nucleic acid wherein the nucleic acid is "sensitive to" the electromagnetic response characteristics of the surrounding medium.

The specification provides guidance for calculating a radiation frequency specific to a calculated wavelength of genomic DNA or mRNA wherein the frequency to be applied is "corrected" for the effects of propagating through a medium, such that when the radiation gets to the DNA or mRNA, it is still "tuned" correctly. The specification discusses the effect of the medium on the frequency, on pages 13-20, and provides several examples for adjusting an applied frequency so that it is still appropriate to the length of the DNA or mRNA after passing through a medium surrounding these. The specification does not disclose anywhere an effect of the frequency on a medium surrounding a DNA or RNA molecule. Further, the specification does not disclose a nucleic acid which is "sensitive" to its surrounding medium, or to the electromagnetic properties of the medium, anywhere. It is well known in the prior art how to determine an emission to "influence" a medium with electromagnetic radiation. For example, one does not need a great deal of skill in the art to determine that "medium" is a better emission value to defrost chicken in a microwave whereas "high" is better for popping

corn; or that "high" is better for boiling (an aqueous medium) whereas "simmer" would be better for melting butter (an organic medium) using a magnetic or electric heating source. However, one skilled in the art would not know if a target nucleic acid in that medium were sensitive to the electromagnetic properties of the medium. In the above example, chicken, corn, and butter all comprise nucleic acids. It is unknown whether the nucleic acids in these "media" are sensitive to the microwaving/heating levels used to cook them. If a medium (e.g. organism or tissue) comprises plural nucleic acid chains, one skilled in the art would have to guess at which nucleic acid in a medium is "sensitive" to the electromagnetic properties of its medium, and/or would have to guess at how to determine whether a particular nucleic acid chain were sensitive. This constitutes undue experimentation.

Due to the lack of guidance in either the instant specification or the prior art for how to determine how to influence a medium surrounding a nucleic acid chain which is sensitive to the electromagnetic response characteristics (properties) of that medium, the claims are not enabled.

Claim Rejections - 35 USC § 112, 2nd para.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 is directed to a method of determining resonant frequencies of electromagnetic emission for influencing a medium surrounding target nucleic id chain, but the claim results in a step of selectively influencing the "target nucleic acid chain". There are no steps of either determining a resonant frequency for influencing a medium nor of actually influencing the medium. As it is unclear what method is actually intended due to the incongruity between the preamble and steps of the claims method, the claim is indefinite.

Claim 1 recites a "medium-sensitive target nucleic acid chain" in lines 19-20. The preamble defines "medium-sensitive" to mean "sensitive to the electromagnetic response characteristics of the surrounding medium"; however, it is unclear WHAT about the nucleic acid chain is sensitive nor in what way the nucleic acid chain is intended to be sensitive. Does the nucleic acid chain change conformation? Does it become more or less accessible to elements of the medium? Does it undergo spontaneous mutation, or is its rate of repair accelerated? Does it begin/stop mitosis and/or meiosis? Etc. As it is unclear what limitation of the target nucleic acid chain is actually intended, the claim is indefinite.

Claims 1 and 2 recite the phrase "length parameter". A length "parameter" is not disclosed or defined anywhere, and it is unclear if what is determined is actually a "parameter". Merriam-Webster's dictionary defines a "parameter" as an arbitrary constant whose value characterizes a member of a system (as a family of curves); or a quantity (as a mean or variance) that describes a statistical population. The specification discloses calculating a length for individual nucleic acids to be affected by

a resonant frequency, not a constant or quantity which is the same (or which is characteristic) of a plurality (population) of nucleic acid chains. As it is unclear what limitation if intended by the phrase "length parameter", the claims are indefinite.

Claim 2 further recites determining a length parameter in lines 1-2, but also recites using a resulting (i.e. calculated value) as a "wavelength parameter". It is unclear what is being determined; i.e. a length parameter, or a wavelength parameter, therefore claim 2 is further indefinite.

Claims 2 and 4-14 depend from claim 1 and are therefore also indefinite for the reasons set forth above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
10/17/05